UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

Before the Honorable Paul J. Luckern

Public Version

In the Matter of CERTAIN RUBBER ANTIDEGRADANTS, COMPONENTS THEREOF, AND PRODUCTS CONTAINING SAME

Investigation No. 337-TA-533

FLEXSYS AMERICA L.P.'S PETITION FOR REVIEW OF FINAL INITIAL AND RECOMMENDED DETERMINATIONS

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TABLE OF CONTENTS **Public Version**

TABLE OF AUTHORITIES Public Version

Cases

Statutes

Other Authorities

Rules

I. INTRODUCTION

Public Version

Complainant, Flexsys America L.P. ("Flexsys") respectfully submits this Petition for Review of *Final Initial and Recommended Determinations* dated February 21, 2006 in this action (the "ID").

The ID held that Respondent Sinorgchem Co. Shandong ("Sinorgchem") made both 4-ADPA and 6PPD using processes covered by the patents-in-suit. It also held that Sovereign Chemical Co. ("Sovereign") imported Sinorgchem's 6PPD into the United States. Thus, it held that Sovereign and Sinorgchem violated Section 1337.

The ID further found that Respondent Korea Kumho Petrochemical Company ("KKPC") purchased 4-ADPA from Sinorgchem, converted it into 6PPD, and sold it for importation into the United States. Without considering the meaning of 19 U.S.C. §1337 (a)(1)(B)(ii), the ID concluded that KKPC did not commit a violation because it did not itself perform all of the steps of the patented process.

For the reasons explained below, the conclusion that KKPC did not commit a violation is contrary to the plain language of Section 1337(a)(1)(B)(ii), and presents issues of first impression that must be decided by the Commission.

A. ISSUES PRESENTED

Is the sale for importation into the United States of an article that was made by a process covered by the claim of a valid and enforceable U.S. patent a violation of 19 U.S.C. §1337(a)(1)(B)(ii), if two entities collectively practiced the steps of that process? The answer is yes.

Is the sale for importation into the United States of an article that was made by means of a process covered by the claim of a valid and enforceable U.S. patent a

violation of Section 1337(a)(1)(B)(ii), even if additional steps were performed. The answer is yes.

B. SUMMARY OF ARGUMENT

By its terms, Section 1337(a)(1)(B)(ii) expressly provides that "unlawful activities" include the "importation . . . [or] the sale for importation" . . . of articles . . . made . . . by means of. . . . a process covered by the claims of a valid and enforceable United States patent." The statutory language bars importation of an **article** made by a process covered by a U.S. patent, and requires only that all steps of the process claim be utilized in the manufacture of the article.

Contrary to KKPC's arguments, Section 1337(a)(1)(B)(ii) does not limit the finding of a violation to those articles in which only one entity practiced all of the steps of the process claim. The violation consists of the act of importing or selling for importation an article made by the claimed process. Where, as here, the imported article is made by a process "covered by the claims of a valid . . . patent," it is immaterial that two entities – in this case Respondents Sinorgchem and KKPC – collectively practiced the patented process.

KKPC sold 6PPD for importation into the United States. The ID concluded that KKPC's 6PPD was made by the four-step process covered by claim 61 of the '063 patent and claim 11 of the '111 patent. It found that the first three steps of the process (which produce 4-ADPA) were performed by Respondent Sinorgchem, and the fourth step that converted 4-ADPA to 6PPD was performed by KKPC. Under these circumstances, the plain language of Section 1337(a)(1)(B)(ii) compels the conclusion that KKPC has violated the statute.

As the result of arguments made by Respondents at pages 51-58 of their post hearing Reply Brief, the ID relied on cases construing 35 U.S.C. §271(a), but did not consider or analyze the statutory language of Section 1337(a)(1)(B)(ii). As a result, it reached the wrong conclusion in this case with respect to KKPC.

Both the Commission and the Federal Circuit have recognized that Section 1337(a)(1)(B)(ii) exclusively governs ITC actions involving the importation of products made by process covered by claims of a valid U.S. patent. *Kinik v. U.S.I.T.C.*, 362 F.3d 1359, 1361-64 (Fed. Cir. 2004).

As is explained below, Section 271(a) applies only to patented processes practiced within the United States. That section imposes liability on persons who practice the process. In contrast, Section 1337(a)(1)(B)(ii), focuses on the article, rather than the person who practiced the process, and makes it unlawful to import articles made outside of the United States by a process patented in the United States. To the extent that case law on Section 271(a) conditions liability on a single entity practicing the invention, it is inapplicable to Section 1337(a)(1)(B)(ii).

Surprisingly, this is an issue of first impression before the Commission. The proper construction of Section 1337(a)(1)(B)(ii) is a straightforward matter of statutory interpretation, and has important ramifications affecting the policy underlying the Tariff Act. Thus, this issue should be reviewed by the Commission pursuant to 19 C.F.R. §210.43(b)(1)(iii).

The ALJ determined that the 6PPD KKPC sold for importation into the United States was made from 4-ADPA Sinorgchem produced using a process covered by claim 30 of the '063 patent and claim 7 of the '111 patent. Thus, it is clear that this 6PPD was

made "by means of" a process covered by these claims. KKPC imported a product produced by a process covered by these claims, regardless of the fact that KKPC practiced an additional process step. This interpretation is fully consistent with the plain language of the statute and the reasoning of the Federal Circuit in cases construing 35 U.S.C. §271(g): *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553 (Fed. Cir. 1996) and *Eli Lilly & Co. v. American Cynanimid Co.*, 82 F.3d 1568 (Fed. Cir. 1996).

II. CONCISE STATEMENT OF FACTS

In this action, Flexsys asserted that the products at issue were made by processes covered by claims 30 and 61 of U.S. Patent No. 5,117,063 ("the '063 patent") and by claims 7 and 11 of U.S. Patent No. 5,608,111 ("the '111 patent").

Claim 30 of the '063 patent and claim 7 of the '111 patent cover three-step methods of making a substance known as "4-ADPA"[1]; claim 61 of the '063 patent and claim 11 of the '111 patent cover a four-step method of making 6PPD.[2]

A comparison of claims 30 and 61 of the '063 patent, which is set forth below, illustrates that the only difference in the claims for producing 4-ADPA and 6PPD is the last step, in which 4-ADPA is "reductively alkylated" to produce 6PPD. The same analysis applies to claims 7 and 11 of the '111 patent.

[1] 4-ADPA is an acronym for "4-aminodiphenylamine." ID at 9, n.3.
[2] 6PPD is an acronym for N-(1,3-dimethylbutyl)-N'-phenyl-p-phenylenediamine. ID at 10.

Claim 30 (Method of making 4-ADPA)	Claim 61 (Method of making 6PPD)
30. A method of producing 4-aminodiphenylamine (4-ADPA) comprising the steps of: a) bringing aniline and nitrobenzene into reactive contact in a suitable solvent system; b) reacting the aniline and nitrobenzene in a confined zone at a suitable temperature, and in the presence of a suitable base and controlled amount of protic material to produce one or more 4-ADPA intermediates; and c) reducing the 4-ADPA intermediates under conditions which produce 4-ADPA.	61. A method of producing alkylated p-phenylenediamines **[6PPD]** comprising the steps of: a) bringing aniline and nitrobenzene into reactive contact in a suitable solvent system; b) reacting the aniline and nitrobenzene in a confined zone at a suitable temperature, and in the presence of a suitable base and controlled amount of protic material to produce one or more 4-ADPA intermediates. c) reducing the 4-ADPA intermediates to produce 4-ADPA; **and** **d) reductively alkylating the 4-ADPA of Step c).**

In this regard, the ID correctly observed that the first three steps of claim 61 of the '063 patent and claim 11 of the '111 patent for producing 6PPD "are essentially identical to the first three steps of said claims 30 [of the '063 patent] and 7 [of the '111 patent]" for producing 4-ADPA. ID at 104.

Respondent Sinorgchem manufactures both 4-ADPA and 6PPD in its plant in China. Respondent Sovereign purchases 6PPD from Sinorgchem and imports it into the United States. ID at 35.

In a well-reasoned opinion with detailed findings on the patent specifications, prosecution history, claim construction, prior art, and the accused processes, the ID concluded that Sinorgchem's process for making 4-ADPA was covered by claim 30 of the '063 patent and claim 7 of the '111 patent ("the 4-ADPA claims"), and that its

process for making 6PPD was covered by claim 61 of the '063 patent and claim 11 of the '111 patent ("the 6PPD claims"). ID at 97.[3]

It is undisputed that Respondent Korea Kumho Petrochemical Co. ("KKPC") purchases 4-ADPA from Sinorgchem. As reflected in the ID, the parties stipulated that "KKPC has sold for importation into the United States 6PPD it owns and produced at its plant in Korea using 4-ADPA purchased from Sinorgchem in China." ID at 35.

The ID concluded that "KKPC has continued to produce commercially 6PPD only from 4-ADPA that it purchases from third party commercial vendors, including Sinorgchem." ID at 103. As mentioned above, the ID found that the 4-ADPA produced by Sinorgchem was made by a process covered by claims of the patents in suit. ID at 97. The ID also concluded that KKPC performs the last step in the patented processes ("reductively alkylating the 4-ADPA") to produce 6PPD: "KKPC produces its commercial 6PPD from 4-ADPA [purchased from Sinorgchem] by the known process of reductive alkylation . . . ." ID at 103.

On February 21, 2006, the ALJ issued the ID, finding a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. §1337, by Respondents Sinorgchem and Sovereign, but not by KKPC. The ALJ found that the processes used by Sinorgchem to produce 4-ADPA and 6PPD are covered by the claims of the patents-in-suit. ID at 97-102. Thus, the ID concluded that Sinorgchem violated Section 1337. In spite of the fact that the ID concluded that KKPC purchases from Sinorgchem 4-ADPA made by a process covered by claim 30 of the '063 patent and by claim 7 of the '111 patent, and that

[3] "The administrative law judge finds that the complainant has established, by a preponderance of the evidence, that the Sinorgchem process to make 4-ADPA and 6PPD literally infringes the asserted claims in issue." ID at 97.

KKPC practiced the additional step in the 6PPD claims (the same step practiced by Sinorgchem), the ID concluded that KKPC did not violate Section 1337(a)(1)(B)(ii) because KKPC did not perform all of the steps of the claims.

III. ARGUMENT

A. Section 1337(a)(1)(B)(ii) Requires Only That The Imported Article be "made . . . by means of . . . a process covered by the claims of a valid and enforceable patent," Regardless of Whether Two Entities Collectively Practice the Process

"[T]he starting point for interpreting a statute is the language of the statute itself. Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive." *Consumer Product Safety Commission v. GTE Sylvania, Inc.*, 447 U.S. 102, 108, 100 S. Ct. 2051, 2056 (1980).

A review of the language of Section 1337(a)(1)(B)(ii) compels the conclusion that the importation of articles made by a process covered by a claim of a U.S. patent is unlawful, even if more than one actor practices the steps of the process.

The statute at issue, Section 1337(a)(1)(B)(ii), reads in pertinent part, as follows:

> **§ 1337. Unfair practices in import trade**
>
> (a) Unlawful activities; covered industries; definitions
>
> (1) Subject to paragraph (2), the following are unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provision of law, as provided in this section:
> * * *
> (B) The **importation** into the United States, the **sale for importation**, or the **sale within the United States after importation** by the owner, importer, or consignee, of articles that--
>
> (i) infringe a valid and enforceable United States patent or a valid and enforceable United States copyright registered under Title 17; or

(ii) are made, produced, processed, or mined under, or by means of, a process covered by the claims of a valid and enforceable United States patent.

(Emphasis added).

There is nothing ambiguous about Section 1337(a)(1)(B)(ii). It bars "importation . . .of articles that . . .(ii) are made . . . by means of. . . . a process covered by the claims of a valid and enforceable United States patent." It requires only that the article be made by a process covered by the claims of a valid U.S. patent. There is no requirement that the steps of the method claim at issue be practiced by only one entity. Section 1337(a)(1)(B)(ii) requires only that each of the steps in the method claim was used to produce the article that is the subject of the Section 1337 investigation.

A review of the legislative history, later legislative comments about Section 1337(a)(1)(B)(ii), and the ITC's *in rem* jurisdictional basis, are all entirely consistent with the plain language of the statute.

1. The Legislative History of the Tariff Act is Consistent with the Plain Language of Section 1337(a)(1)(B)(ii)

Section 1337(a)(1)(B)(ii) was enacted on August 23, 1988, amending former Section 1337(a), which was enacted in 1940. The legislative history of both sections was discussed at length in *In re Matter of Certain Erythropoietin*, No. 337-TA-281, 1989 WL 608775 (1989),[4] *aff'd sub nom, Amgen v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532 (Fed. Cir. 1990).

In 1940, Section 1337(a) was enacted in response to the decision of the Court of Customs and Patent Appeals in *In re Amtorg Trading Corp.*, 75 F.2d 826 (C.C.P.A.

[4] The August 23, 1988 amendments did not alter the scope of former § 1337(a) as it applied to importing a product made by a process covered by a U.S. patent. *Amgen,* 902 F.2d at 1539.

1935),[5] cert. denied, 296 U.S. 576 (1935). *Id.* In *Amtorg* the CCPA held that it was not a violation of Section 1337 for someone to import into the US a mineral that was mined in the Soviet Union using a mining process covered by a U.S. process patent. *In re Amtorg Trading Corp.*, 75 F. 2d at 827.[6]

The legislative history of original Section 1337(a) demonstrates that Congress had a visceral reaction to the *Amtorg* decision. The following comment from the American Bar Association is an example:

> Fundamentally, the question is whether or not it is an unfair act to steal the process produced by the brains of Americans and published in their patents, and to use these processes to destroy the business of Americans. I think the answer is that we should make reasonable effort to protect American patentees against ruinous competition based upon inventions made and published by them. Obviously the proposed amendment **affects only goods brought in this country**. It does not restrain the use abroad of processes patented in this country, but merely **restrains the importation of the products of this process** brought into this country in ruinous competition with products made in this country employing these processes.

S. Rep. No. 76-1903 at 2 (1940) (emphasis added).

Similarly, both the House and Senate Reports provide that:

> This bill is designed to correct the present problem which was created when the [CCPA] . . . held that the **importation of products made abroad in accordance with a United States process patent** without consent of patentee was not regarded as an unfair method of competition.

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[5] S. Rep. No. 76-1903 at 1-2 (1940). The ID in the *Erythropoietin* case also contains an excellent and perhaps the most comprehensive summary of the legislative history of these provisions at Appendix A to the Initial Determination.

[6] In a prior decision, *In Re Northern Pigment Co.*, 71 F.2d 447 (C.C.P.A. 1934), the CCPA had held that such importations constitute unfair trade practices. In *Amtorg*, however, the Court reversed itself, and held such importations do not constitute unfair trade practices. *In re Amtorg Trading Corp.*, 75 F. 2d at 570.

S. Rep. No. 76-1903 at 1 ; H.R. Rep. No. 76-1781 at 1 (1940) (emphasis added).

Accordingly, in 1940, Congress passed bill H.R. 8285, 3d Cong. (1940), which was titled: "**Limit[ing] the importation of products produced,** processed, or mined **under process covered by United States Patents; . . . .**" S. Rep. No. 76-1903 at 1 (emphasis added). This bill was then signed into law on July 2, 1940,[7] enacting 19 U.S.C. § 1337(a), which read as follows:

> The importation for use, sale, or exchange of a product made, produced, processed, or mined under or by means of a process covered by the claims of any unexpired valid United States letters patent, shall have the same status for the purposes of section 1337 of this title as the importation of any product or article covered by the claims of any unexpired valid United States letters patent.

The substance of this bill, its title, and its legislative history all focus on preventing the importation of a product made by a patented process to reverse the CCPA's decision in *Amtorg*. The statute and its legislative history are void of any requirement that the product be produced by only one entity.

Thus, former Section 1337(a) prohibited in pertinent part, "[t]he importation . . . of a product made . . . by means of a process covered by the claims of any unexpired valid United States letters patent," language which is virtually identical to the operative part of Section 1337(a)(1)(B)(ii).

2. The Legislative History of the Process Patents Amendment Act Supports Flexsys' Interpretation of Section 1337(a)(1)(B)(ii)

For many years, Section 271 of the Patent Act did not prohibit the importation of a product made outside of the U.S. by a process claimed in a U.S. patent. From its

[7] *See In re Certain Recombinant Erythropoietin*, Inv. No. 337-TA-281, 1989 WL 608775 (Jan. 10, 1989) Initial Determination, Appendix A, at 6 (USITC Publication 2186 May 1989).

passage in 1952 until 1988, the portion of Section 271 relating to direct infringement of process claims read as follows:

> (a) Except as otherwise provided in this title, **whoever** without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

Infringement of Patents, 66 Stat. 811, (July 19, 1952) (Emphasis added).

In 1988, Congress passed the Process Patent Amendment Act,[8] resulting in the addition of 35 U.S.C. § 271(g), which provided a remedy in civil actions against the importation of "a product made by a process patented in the United States." One of the issues that arose during the debate over the Process Patent act was the extent and type of protection that Section 1337(a)(1)(B)(ii) provided to process patent holders. In addressing this issue the Senate Report acknowledged that Section 1337(a)(1)(B)(ii) was *in rem* in nature, and thus violations arose regardless of whether there was knowledge of the process used to make the product. Specifically, the Senate Report acknowledges that:

> [The] ITC exercises *in rem* rather than *in personam* jurisdiction: its orders go only to the goods themselves that are being imported and used or sold here. These experts contend that this focus on the goods is fair because once the goods have passed beyond the hands of the original manufacturer, the persons handling them can no longer be assumed to be knowledgeable of the process used to make the goods.

S. Rep. No. 100-83 at 39 (1987).

Thus, Congress reconfirmed that Section 1337(a)(1)(B)(ii) is *in rem* and focused solely on the product being imported, rather than the actors who carried out the patented process overseas.

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[8] Process Patent Amendment Act, Pub. L. No. 100-418 (August 23, 1988).

In 1994, Congress amended Section 271(a) of the Patent Act,[9] as the result of the April 1994 Uruguay Round trade agreements, which included an agreement on the "Trade-Related Aspects of Intellectual Property" (TRIPS). As is explained in the CHISUM ON PATENTS treatise:

> The TRIPS Agreement's Article 28 provided: "a patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or *importing* ... for these purposes that product ... ." Existing United States patent law did not include importation among a patent owner's exclusive rights to a patented product (though, ironically, the 1988 Process Patent Amendment Act had made importation of an unpatented product made by a patented process an exclusive right.) To conform United States law to Article 28, the 1994 Uruguay Agreements Amendments Act's 532(a)(1) amended Section 154 to add "importing the invention into the United States," and its Section 533(a) amended *35 U.S.C. Section 271* to add "import into the United States" in various subsections. Section 533(b) made "conforming amendments" to add importation.

Donald S. Chisum, 5 CHISUM ON PATENTS §16.02 [8] (2004) (Emphasis added). Thus, CHISUM explained that prior to the effective date of the 1994 amendment, Section 271(a) did not prohibit importation of a patented product, but Section 271(g) prohibited the importation of a product made by a patented process. Thus, the "importation" language was added to Section 271(a) to prohibit the importation of patented products. The importation language in Section 271(a) does not apply to processes for producing products, which is important for reasons that are explained below.

[9] Process Patent Amendment Act, Pub. L. No. 103-465, §533(a), 108 Stat. 4988 (Dec. 8, 1994).

3. The ITC's *in rem* jurisdiction is Consistent With Flexsys' Interpretation of Section 1337(a)(1)(B)(ii)

It is well-settled that the ITC's jurisdiction in matters under Section 1337(a)(1)(B)(ii) is *in rem* in nature, rather than *in personam*. *See e.g., Sealed Air Corp. v. U.S. International Trade Commission*, 645 F.2d 976, 986-987 (CCPA 1981). Thus, writing knowledge and joint activity requirements, which are *in personam* in nature, into this subsection is contrary to the ITC's jurisdictional basis. KKPC's arguments in its post hearing reply brief would require the Commission to improperly interpret Section 1337(a)(1)(B)(ii) to restrict its jurisdiction.

The *in rem* nature of ITC actions, as recognized by the Federal Circuit and the legislative history discussed above, provides an important safeguard against foreign competitors who may not fully disclose their activities during ITC proceedings. *E.g., Sealed Air Corp.*, 645 F.2d at 987-98.

In this case, KKPC argued that it did not know the details of Sinorgchem's process for producing 4-ADPA because Sinorgchem would not disclose them. At the hearing, however, KKPC's witness, Mr. Lim, admitted on cross-examination that KKPC failed to produce relevant documents that were expressly sought by Flexsys.

> A. * * * "[A]s far as meeting minutes are concerned, I believe that there are a lot of them hanging around.
> Q. Well, you didn't produce any of those meeting minutes in this case, did you?
> A. That is right. Those particular minutes I'm referring to were drafted in Korean, and they were internal purpose minutes, so we did not produce those. But they are there in the way they were printed back then."

(Tr. 1613:23 – 1614:11.) Given the admission that KKPC withheld documents, it is impossible to ascertain whether KKPC was telling the truth about its alleged lack of knowledge of Sinorgchem's process.

Section 1337(a)(1)(B)(ii) must be construed to mean exactly what it says. Otherwise, unscrupulous foreign infringers who pirate U.S. patented technology will have a license to engage in all-too-familiar shell games to avoid violating Section 1337(a)(1)(B)(ii). As a result, the Commission will repeatedly be required to parse through arguments – like the one KKPC made here – that a respondent does not know what process their co-respondent is practicing.

KKPC's strained interpretation of Section 1337(a)(1)(B)(ii), and the result of the ID with respect to KKPC invites any party in a similar position to play "ostrich." Such a result is contrary to the clear language of Section 1337(a)(1)(B)(ii), its legislative history, and a substantial body of law precluding the "ostrich" defense. For example, even in criminal cases, where the evidentiary standard is "beyond a reasonable doubt," courts have given the so-called "ostrich" instruction "when the defendant claims a lack of guilty knowledge and there is evidence that supports an inference of deliberate ignorance or willful blindness." *U.S. v. Wilson*, 134 F.3d 855, 868 (7th Cir. 1998).

Accordingly, the Commission should find that Section 1337(a)(1)(B)(ii) means exactly what it says. To do otherwise would substantially eliminate a key part of the legislative protection for owners of U.S. process patents.

4. The Initial Determination Ignored Section 1337(a)(1)(B)(ii)

In finding that KKPC had not committed a violation, the ID did not refer to Section 1337(a)(1)(B)(ii). Instead, it analyzed "infringement" under 35 U.S.C. §271(a) and (g), for the proposition that "to directly infringe a process claim, a party must perform each and every recited step of the claimed process," ID at 93, *citing Avery Dennison Corp. v. UCB Films PLC*, No. 95 C 6351, 1997 WL 665795 at 2 (N.D. Ill. Oct.

20, 1997). *Avery,* however, does not support this conclusion, as is discussed in Section 7, below.

As is clear from the legislative history of Section 271, set forth above, Section 271(a) does not apply to processes practiced outside of the United States, and the "import" language, which was added by amendment in 1994 applies only to products. Thus, the ALJ's reliance on *Avery* for the above proposition was misplaced.

It is well settled that Section 1337(a)(1)(B)(ii) governs Section 1337 actions brought against products made abroad by processes covered by valid United States patents. *Kinik v. U.S.I.T.C.*, 362 F.3d 1359, 1361-64 (Fed. Cir. 2004) (holding that the "defenses" in 35 U.S.C. §271(g) are not available in a Section 1337 action). In addition, the ALJ ignored the differences between Section 271(a) and Section 1337(a)(1)(B)(ii).

Section 271(a) imposes liability on the person who practices a patented process in the United States: "**[w]hoever** without authority makes, **uses,** offers to sell or sells any patented invention **within the United States** or imports into the United States any patented invention. . . infringes the patent." (Emphasis added). The Federal Circuit has held that only the term "uses" applies to process claims. *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1317-18 (Fed. Cir. 2005).[10] "Congress has consistently expressed the view that it understands infringement of method claims under section 271(a) to be limited to use." *NTP*, 418 F.3d at 1319. Thus, it is clear that Section 271(a)

[10] In the context of the on sale bar of 35 U.S.C. §102, the Federal Circuit has observed that,"[u]nder section 271(a), the concept of "use" of a patented method or process is fundamentally different from the use of a patented system or device." *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (recognizing 'the distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps... [A process] consists of doing something, and therefore has to be carried out or performed.').

imposes liability on a person or entity who **uses** a method covered by claims of a valid patent in the United States.

In sharp contrast, Section 1337(a)(1)(B)(ii) prohibits importation or sale for importation of "articles . . . made . . . by means of . . . a process covered by the claims of a valid United States patent." Thus, the key question under Section 1337(a)(1)(B)(ii) is not who has practiced the process, but rather, whether the article that is the subject of importation has been made by the patented process. For this reason, Section 1337(a)(1)(B)(ii) makes it unlawful to import or sell for importation **articles**, if the **articles** are made by a patented process.

Without citing Section 1337(a)(1)(B)(ii), the ID incorrectly held that "Flexsys must prove that KKPC performs all of the recited steps of the asserted claims." ID at 104. For the reasons set forth in Section III.A., above, this is not the standard under Section 1337(a)(1)(B)(ii). The only "authority" the ID cited for this erroneous proposition was *Canton Bio-Medical v Integrated Liner Techs., Inc.*, 216 F.3d 1367, 1370 (Fed. Cir. 2000). *Canton*, however, does not stand for that proposition. *Canton* involved an issue of prosecution history estoppel. *Id.* at 1371. It did not address the question of whether a Respondent in a Section 1337 action was required to practice all of the steps of a patented process. None of the other cases cited in the ID addresses this issue.

It appears that most of the ID's analysis of this issue came from Respondents' post trial reply brief. Flexsys did not have an opportunity to reply to that brief. We point out in the following section that the arguments Respondents made were wrong as a matter of law.

5. Respondents' Proposed Interpretation of Section 1337(a)(1)(B)(ii) is not Supported by the Authorities it Cited in its Post Hearing Briefs

The ALJ was apparently misled by incorrect legal arguments in Respondents' reply brief. Perhaps the most egregious misstatement of the law in Respondents' Reply Brief is its argument on page 53:

> Although § 1337(a)(1)(B)(ii) does not use the word "infringement" *per se*, it contains the statutory language that defines infringement. Thus, for a violation to be found, §1337(a)(1)(B)(ii) requires that an "article" be "made" or "produced" by a process "covered by the claims" of a United States patent. That language is nearly identical to the corresponding language of 35 U.S.C. §271(a), which defines "mak[ing]" or "import[ing]" a "patented invention" as an act of infringement, and the corresponding language of §271(g), which defines infringement as importing a "product . . . made by a process patented in the United States. . . ."

This argument is chock-full of errors.

The legislative history discussed above demonstrates that the "imports" phrase of Section 271(a) does not apply to process claims. Further, a noted treatise has observed that the "imports" language of the 1994 amendment applies only to products. Chisum, *supra*, §16.02 [8]. Further, the Federal Circuit has recognized that "infringement of method claims under section 271(a) [is] limited to use." *NTP*, 418 F.3d at 1319. In *Joy Technologies, Inc. v. Flakt, Inc.*, 6 F.3d 770, 774-775 (Fed. Cir. 1993), decided one year before the 1994 amendment, the Federal Circuit unequivocally stated that "a method claim is not infringed by the sale of an apparatus even though it is capable of performing only the patented method." If "sale" of invention does not apply to process claims, then neither can the "import" of a "patented invention."

The legislative history of Section 271(a), combined with the *NTP* and *Joy* decisions compel the conclusion that the "imports" clause of Section 271(a) does not apply to method claims practiced outside of the United States. In sharp contrast, the language of both Section 271(g) and Section 1337(a)(1)(B)(ii) prohibit importation of a product made by a patented process.

Respondents incorrectly argue at page 54 of their Reply Brief that *Amgen,* 902 F.2d at 1538 supports their argument. Respondents are wrong. In *Amgen*, Chugai imported recombinant erythropoietin (rEPO). Amgen's patent did not cover rEPO or the method Chugai was using to make it. *Id.* at 1534. Instead, Amgen's patent covered host cells that could be used to produce rEPO. *Id.* The Federal Circuit held that the phrase "process covered by claims of a valid and enforceable United States patent" did not apply to the Chugai's production of rEPO outside of the United States. *Id.* at 1540. In reaching this result, it held that the claims of Amgen's patents were not process claims. *Id.* at 1535. "A host cell claim does not 'cover' intracellular processes any more or less than a claim to a machine 'covers' the process performed by that machine." *Id.* at 1537-38. Thus, *Amgen* held that the importation of a product made by the use of a patented product did not invoke Section 1337(a)(1)(B)(ii). *Amgen,* 902 F.2d at 1539.

Amgen does not stand for the proposition, argued at page 54 of Respondents' reply brief, that "the 'covered' language in §1337(1)(a)(B)(ii) . . . effectively means 'infringed.'" On the contrary, *Amgen* construed the meaning of the phrase "a process covered by the claims of a . . . patent" in Section 1337(a)(1)(B)(ii), but it did not construe it to mean "infringement." *Id.* at 1538. It concluded, "we are of the opinion that in normal parlance among patent lawyers, to whom patent statutes are directed, a patent

'covering' a process is a patent containing at least one claim defining a process." *Id.* *Amgen* also the explained that the phrase "a patent covering a process" in Section 1337(a)(1)(B)(ii) has the same meaning as "process patented" as that term is used in 35 U.S.C. § 271. *Id.* at 1540, n. 13.

Respondents' argument that Section 1337(c) precludes Flexsys' statutory interpretation of Section 1337(a)(1)(B)(ii), is nothing more than a red herring. Section 1337(c) provides in part that "[a]ll legal and equitable defenses may be presented in all cases." In this context, "defenses" refers to defenses that are available under the applicable statute. Indeed, an argument similar to the one KKPC makes here was rejected in *Kinik*, 362 F.3d at 1361-64 (holding the defenses of Section 271(g) are not available in a Section 1337(a)(1)(B)(ii) action).

Citing three inapplicable cases decided under Section 271(a), Respondents incorrectly argue that Flexsys must prove that "KKPC, acting alone or in concert with Sinorgchem," carries out all of the steps of the patented process. *RF Delaware, Inc. v. Pacific Keystone Techs., Inc.*, 326 F.3d 1255, 1267 (Fed. Cir. 2003) (discussing whether defendant was liable under 35 U.S.C. §271(b) or (c)); *Canton Bio-Medical, Inc. v. Integrated Liner Techs, Inc.*, 216 F.3d 1367, 1370 (Fed. Cir. 2000) (analyzing issue under doctrine of equivalents); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773 (Fed. Cir. 1993). These cases are inapplicable because they were not decided under Section 1337(a)(1)(B)(ii) or Section 271(g). At most, those cases stand for the settled proposition that under Section 271(a), a claim for a process is infringed if all of the steps of the patent claim read on the process practiced by the accused infringer in the United States. Further, in each of those cases, only one entity was accused of practicing the process.

6. The ID's Conclusion Is Contrary to the Policies Underlying Section 1337(a)(1)(B)(ii)

The ID results in the following, illogical result:

Result (1) Sinorgchem, who practices both the claimed process for making 4-ADPA (steps 1-3) and the claimed process for making 6PPD (steps 1-4) and who sells 6PPD to Sovereign for importation into the U.S., violates Section 1337.

Result (2) Sovereign, who purchases 6PPD from Sinorgchem for importation into the U.S., but who does not practice any steps of the claimed processes, violates Section 1337.

Result (3) KKPC, who purchases the 4-ADPA from Sinorgchem that Sinorgchem made by the patented process (steps 1-3), practices step 4 to convert it to 6PPD, and sells it for importation into the U.S., does not violate Section 1337.

There can be no dispute that the ID has determined that articles imported into the United States in Results (1) – (3) are all made by processes covered by the claims of the patents in suit. Sovereign has violated Section 1337 (Result (2)) even though it did not practice any of the steps, but KKPC has not violated Section 1337 (Result (3)) even though it practiced step 4.

The Commission has long held that importers, such as Sovereign, are liable for importation of a product made by a process covered by the claims of a U.S. patent. There is no policy reason why an entity who practices the final step of a process should fare better than an importer who practices none of the steps, especially where, as here, the articles imported by both were made by the same steps of the patented process.

The result of the ID is a clear invitation to foreign entities to eviscerate the provisions of Section 1337(a)(1)(B)(ii) by conspiring to separately, but collectively, practice the steps of processes covered by U.S. patents. The difficulty of obtaining discovery from foreign respondents is illustrated by the testimony of Mr. Lim of KKPC,

who testified at trial that KKPC did not produce relevant documents, admitting that "they were internal purpose minutes, so we did not produce those." (TR 1613:23-1614:11.)

Moreover, KKPC's protests that it did not know that Sinorgchem was practicing a process covered by the first three steps of claims 61 of the '063 patent and Claim 11 of the '111 patent are belied by several facts. First, KKPC has known about Flexsys' patented process since before 1995, when KKPC asked Monsanto to build a plant using the "PPD2" process – the process covered by the '063 patent. (CX 166).

Second, by visiting Sinorgchem and reviewing Sinorgchem's published patent applications, Flexsys was able to determine that Sinorgchem was practicing a process covered by its patents, and filed a Complaint in the Northern District of Ohio, and then the Complaint in this action, both of which recite the evidence obtained through Flexsys' investigation. As a customer, KKPC had an even better opportunity to determine that Sinorgchem was practicing a process that was covered by the claims of Flexsys' patents. KKPC was put on notice through the lawsuit in Ohio, and through the Complaint in this action, and yet it still argued that it did not know what process Sinorgchem was practicing.

Third, the remedy provided by this action is prospective. As the result of the ALJ's decision, KKPC and the attorneys representing it in this action now know that Sinorgchem's process for making 4-ADPA is covered by claim 30 of the '063 patent and by claim 11 of the '111 patent. If knowledge is a requirement (and we do not concede that it is), KKPC has such knowledge now, and should be held in violation of Section 1337(a)(1)(B)(ii).

7. The *Avery* and *DuPont* Cases Interpreting 35 U.S.C. § 271(g) Support Flexsys' Interpretation of Section 1337(a)(1)(B)(ii)

The controlling statute for evaluating KKPC's violation is 19 U.S.C. § 1337(a)(1)(B)(ii). It is not 19 U.S.C. § 1337(a)(1)(B)(**i**) or 35 U.S.C. §§ 271(a).

Contrary to the arguments KKPC made in its post-hearing reply brief, *Avery*, 1997 WL 665795 at *1, does not support the conclusion reached in the ID. *Avery* favorably cited E.I. *DuPont v. Monsanto Co.*, 903 F. Supp. 680 (D. Del. 1995) *aff'd on other grounds*, 92 F.3d 1208 (Fed. Cir. 1996), a case in which a violation of Section 271(g) was found where two different defendants collectively practiced steps of a process, but neither practiced all of the steps. *Avery* would have decided the case the same way if the facts had been consistent with those in the *DuPont* case. Thus, *Avery* and *DuPont* interpret § 271(g) in a way that is consistent with Flexsys' proposed construction of Section 1337(a)(1)(B)(ii) and consistent with the conclusion that KKPC's importation of 6PPD violates Section 1337(a)(1)(B)(ii).

As noted above, the ALJ correctly found that KKPC's 6PPD was made by the steps of claim 61 of the '063 and claim 11 of the '111 patent. Sinorgchem performed the majority of the claimed steps[11] and KKPC performed the final claimed step,[12] resulting in the finished product – 6PPD.[13] Under this scenario, KKPC should be liable for

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[11] ID at 97-102. *See also* CBr at 61-63, CRRBr at 40, and CFF 387-430; all of which are incorporated by reference herein.

[12] ID at 103-04 finding that KKPC uses the same reductive alkylation process of the patents to make its 6PPD, which KKPC calls Kumanox 13 – "KKPC's witnesses Lim and Kim demonstrated that KKPC . . . only carries out the **final reductive alkylation** step of the 6PPD process claims." (emphasis added). *See also* CBr at 67, CRRBr at 46-48, and CFF 466-77; all of which are incorporated by reference herein.

[13] The ALJ determined that the process steps were literally met, and thus did not need to address Flexsys' argument that Sinorgchem and KKPC also infringed those claims under the doctrine of equivalents, under Sinorgchem's and KKPC's proposed claim

infringement of these claims under § 271(g) because it imports into the US a product made by the steps of those claims. No further evidence or findings relating to knowledge, joint activity, etc., would be required for a finding of infringement under § 271(g).[14]

To understand the *Avery* case relied upon by KKPC, (hereinafter *Avery II*) the earlier opinion of the court in that case must also be considered (hereinafter *Avery I*). In *Avery I*, the court was presented with summary judgment motions for non-infringement under §§ 271(a),(b) & (c). *Avery Dennison Corp., v. UCB Films PLC.*, No. 95 C 6351, 1997 WL 567799, *1 (N.D. Ill. Sept. 4, 1997) (*Avery I*). Avery, the patentee, had asserted a method patent for making multilayered films against UCB Films. *Id.* at *2. Thus, the *Avery I* Court characterized the relationship of the parties as follows: UCB purchases film products from its subsidiary in Great Britain and sells the products to customers in the United States referred to as "'laminators,"' who perform certain steps in the process and sell the resulting product to companies referred to as "converters," who perform the remaining steps. *Id.*

The court determined that UCB only performed the first step in the four of five step claimed process, and as such, had not produced the final product by the claimed process. *Id.* at 3. Thus, the court found that UCB was not a direct infringer under § 271(a). *Id.* at 4. However, because the "laminators" and "converters" performed the

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construction. Flexsys does not waive its doctrine of equivalents argument and reasserts it herein and incorporates by reference CBr at 63-67, CRRBr at 40-46, and CFF 431-65.

[14] The cases cited by KKPC relating to knowledge of another's process, joint activity, and collaborative activity by multiple parties practicing the claims of a patent process, all relate to an infringement analysis under 35 U.S.C. § 271(a), which is not at issue here.

remaining steps of the claimed process, the court denied summary judgment of non-infringement under Section 271(b) & (c). *Id.*

Avery II, which is relied upon by KKPC, is based upon a "request for clarification" of *Avery I, and* specifically for the court to apply Section 271(g). *Avery*, 1997 WL 665795 at *1. (*Avery II*). Citing the *DuPont* case, the *Avery II* Court found non-infringement under Section 271(g) because the defendant only had produced an *intermediate product* but had not produced the *final product* of the claimed process:

> Plaintiff argues that defendant is also liable for infringement under *35 U.S.C. § 271*(g). However, like § 271(a), § 271(g) imposes liability for direct infringement. *E.I. DuPont de Nemours and Co. v. Monsanto Co., 903 F. Supp. 680, 733-34 (D. Del. 1995).* n4 As this court found in its prior opinion, plaintiff cannot show that defendant directly infringed either process patent in suit under § 271(a), and the court finds that the same reasoning applies to § 271(g). *See* opinion at 5. Both sections deal with direct infringement; § 271(a) deals with the production, use or sale of patented inventions, while § 271(g) deals with the importation, sale, or use of products made by a process patented in the United States. **Because defendant is alleged to have performed at most an initial step of the process patent, it cannot be held liable for direct infringement from sale of the final product.**

Id. at *2. (*Avery II*) (emphasis added).

Thus, the facts in *Avery II* are substantially different from the facts before the Commission in the present case. In the present case, KKPC is not performing an intermediate step. To the contrary, it is undisputed that KKPC performs the **final step** in the process and sells for importation into the US the **final product** – 6PPD. Thus, KKPC's characterization of *Avery II* at pages 41-42 of its post hearing reply brief was grossly inaccurate.

Moreover, the *Avery II* Court, in *dicta*, addressed the situation presently before the Commission, and suggested that under the present facts there should be infringement under § 271(g):

> Plaintiff asserts that in *DuPont* the court found infringement liability under § 271(g) even though the infringer performed only one of several patented steps and did so outside the United States, and that defendant is therefore liable under § 271(g). However, **it was the final step that the infringer performed and it was the sale of the infringing product, not the performance of the one step, that gave rise to § 271(g) liability**. *DuPont, 903 F. Supp. at 734*

Id. at *2 n. 4. (*Avery II*) (emphasis added).

The *DuPont* case, relied upon in *Avery II,* expressly found liability under § 271(g) in an analogous situation. *DuPont,* 903 F. Supp. at 734. The *DuPont* case involved a process patent for making stain resistant nylon fibers, which could be used in carpeting. *Id.* at 688. In this case, there were two separate entities that performed the steps of the patented process. Monsanto performed the first step of the process, making a copolymer. *Id.* at 720. CaMac performed the second and third steps, adding color and spinning the fibers, and then returned the final product to Monsanto for sale.[15] *Id.* at 720-21.

There was no evidence that Monsanto and CaMac, the entities carrying out the steps of the patented process, shared any information. *Id.* at 722, 733 n. 65. In fact, the *DuPont* Court found that CaMac controlled its information very closely and did not share that information with others. *Id.*

[15] BASF was also a defendant in this case and had a similar relationship with CaMac. BASF practiced the first step, CaMac practiced the second and third steps and BASF sold the finished product. *DuPont*, 680 F. Supp. at 720-21.

Under these facts the *DuPont* Court found that it was unnecessary to evaluate Monsanto's conduct under § 271(a), because § 271(g) applied to the final product irrespective of who made that product. *Id.* at 734. Thus, the *DuPont* Court held:

> Monsanto manufactures its 46BJ copolymer and ships it to CaMac. CaMac then adds pigment to the copolymer and spins it into fibers. Monsanto then sells these fibers under the name ULTRON SD. **Because the process used to manufacture the forty-three accused ULTRON SD BCF fibers infringes the Anton patent, the Court finds that Monsanto is clearly liable under § 271(g) for selling these fibers.**

Id. at 733-34 (emphasis added).

Thus, in the *DuPont* case, the court found liability under § 271(g) based *solely* on Monsanto's sale of the final product, which was made by the steps of the patented process. *Id.* Moreover, liability was found even though Monsanto did not perform the final step of the claimed process. *Id.* In the present case, the facts for finding liability are even more compelling. Here, KKPC not only imports the final product, which the ALJ found is made by the claimed process, it also performs the final step of that claimed process to obtain that product.

In this respect, the language of Section 271(g) and Section 1337(a)(1)(B)(ii) are strikingly similar, as shown in the table below.

Section 271(g)	**Section 1337(a)(1)(B)(ii)**
"Whoever without authority imports into the United States . . . a product which is made by a process patented in the United States shall be liable as an infringer. . . ."	(1) * * * [T]he following are unlawful * * * "importation . . .of articles that . . .(ii) are made . . . by means of. . . . a process covered by the claims of a valid and enforceable United States patent."

Neither Section 271(g) or Section 1337(a)(1)(B)(ii) includes any words conditioning liability on one actor practicing all of the steps of the claims. The cases

construing Section 271(g) support Flexsys' proposed interpretation of analogous language in Section 1337(a)(1)(B)(ii). Although the "defenses" in Section 271(g) are not applicable to ITC actions (*See Kinik,* 362 F.3d at 1361-64), the courts' interpretation of parallel language in Section 271(g) should be persuasive with respect to the proper interpretation of Section 1337(a)(1)(B)(ii).

8. KKPC's Argument that the Provision "A Process Covered By" in Section 1337(a)(1)(B)(ii) Requires that an Importer Alone Perform All the Patented Steps, has been Rejected by Courts' Interpretation of that Provision

Respondents erroneously argued that Flexsys must prove that KKPC alone performs all steps of an asserted claim to establish a violation under Section 337 of the Tariff Act, even though KKPC admits that it purchases its 4-ADPA from Sinorgchem (RFF 9.141) and that it "carries out the reductive alkylation step of claim 61 of the '063 patent and claim 11 of the '111 patent. Respondents' Brief at 57, 63.

In attempt to justify their requirement, Respondents pointed to the language in the statute that restricts importation of articles that are produced by "a process 'covered' by the claims of a valid and enforceable U.S. patent." *Id.* The term "covered," however, does not require a finding that an importer alone performs all of the steps of a patented process. In *In re Erytropoietin*, 1989 WL 608775 at *7, Judge Harris held that "'covered by the claims' refers to matters within the coverage or penumbra of the claims at issue."

The Federal Circuit has explained that in the Tariff Act, "a patent 'covering' a process is a patent containing at least one claim defining a process." *Amgen*, 902 F.2d at 1538. Essentially, the term "a patent covering a process" has the same meaning as "process patent" as that term is used in 35 U.S.C. § 271. *Id.* at 1540, n. 13. As we have

pointed out above, the plain language of the Tariff Act does not require a finding of direct infringement under 35 U.S.C. §271(a) by the importer to establish a violation.

Given the foregoing, there can be no question that KKPC has sold for importation a product made by means of a process covered by claim 61 of the '063 patent and by claim 11 of the '111 patent.

B. Alternatively, KKPC Violated The Tariff Act By Selling For Importation Into The United States 6PPD Made "By Means Of" A Process Covered By Claim 30 Of The '063 Patent And Claim 7 Of The '111 Patent

The ALJ specifically found that Sinorgchem's 4-ADPA was made by a process covered by claim 30 of the '063 patent and claim 7 of the '111 patent. ID at 101-102. He also found that KKPC purchased Sinorgchem's 4-ADPA, performed an extra process step to convert it to 6PPD, and sold the resulting 6PPD for importation into the United States. ID at 103, n.34.

Unquestionably, the 6PPD KKPC imported into the United States was made by a process covered by claim 30 of the '063 patent and claim 7 of the '111 patent. It does not matter that KKPC performed an extra process step. The preambles of both claim 30 of the '063 patent and claim 7 of the '111 patent include the word "comprising." In patent parlance,

> The signal that additional steps may be performed in carrying out a claimed method is the word "comprising." *See Vivid Technologies, Inc. v. American Science & Engineering, Inc.*, 200 F.3d 795, 811, 53 USPQ2d 1289, 1301 (Fed.Cir.1999) (the signal "comprising" is "generally understood to signify that the claims do not exclude the presence in the accused apparatus or method of factors in addition to those explicitly recited"); *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271, 229 USPQ 805, 812 (Fed.Cir.1986) (stating "the general proposition that an accused method does not avoid literally infringing a method claim having the transitional phrase 'which

comprises' (or 'comprising') simply because it employs additional steps")

Smith & Nephew, Inc. v. Ethicon, Inc., 276 F.3d 1304, 1311 (Fed. Cir. 2001).

In this regard, KKPC is in no different position than Respondent Sovereign. Sovereign did not practice the process that made the product it imported, but because the product was made by a process covered by the patents in suit, Sovereign violated Section 1337(a)(1)(B)(ii). KKPC imported 6PPD made by the process of claim 30 of the '063 patent and claim 11 of the '111 patent. Like Sovereign, KKPC did not practice the process covered by either claim, but it is liable because it sold the resulting product for importation into the United States in violation of Section 1337(a)(1)(B)(ii).

KKPC cannot argue that its performance of an additional step changed the product, because that defense is not available under Section 1337(a)(1)(B)(ii). *Kinik,* 362 F.3d at 1361-64.[16] KKPC thus violated Section 1337(a)(1)(B)(ii), because it sold for importation into the United States 6PPD that was made by "means of a process" covered by the claims of valid and enforceable patents.

The ALJ also did not address this question of KKPC's violation of Section 1337, although it was expressly raised by Flexsys in its December 16, 2005 Post-Hearing Reply Brief. CRRBr, at 48. The ALJ considered only whether KKPC "infringed" claim 61 of the '063 patent and claim 11 of the '111 patent by its production of 6PPD, not whether KKPC violated Section 1337 simply by selling for import 6PPD that was made by means

[16] Moreover, as noted *infra* in Section A, this additional step is a patented step in a claimed process. Thus, if the Commission were to accept Respondents' interpretation of Section 1337(a)(1)(B)(ii) it would be permitting an importer to avoid a violation, because the importer practiced an additional step that was covered by a patented process. Such a result is clearly not supported by any fair reading of that statute.

of Sinorgchem's process for producing 4-ADPA found to be covered by claim 30 of the '063 patent and claim 7 of the '111 patent.[17]

While it is true that Sinorgchem and not KKPC performed all the steps of claim 30 of the '063 patent and claim 7 of the '111 patent in producing its 4-ADPA, KKPC's violation here is no different than that of any other owner, importer, or consignee that imports, sells for import, or sells after importation an article found to be made by means of a process covered by a valid and enforceable patent. The violation is in the act of the importation or sale, not in making the article that was produced by the covered process.[18]

This particular investigation presents the strongest case for finding the product actually sold for import into the United States to be made "by means of" a process covered by the claims of a valid and enforceable U.S. patent. KKPC's 6PPD here was

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[17] Flexsys' position is that KKPC violated 19 U.S.C. § 1337(a)(1)(B)(ii) solely by its sale for import of 6PPD. As such, Flexsys does not see the question as one of remedy as to whether any limited exclusion order against Sinorgchem that includes its 4-ADPA should be expanded to include 6PPD as a downstream product. However, Flexsys does take issue with the loose language in footnote 42 of the ID. ID at 131, n.42. Complainant in Stipulation SX-6 did not agree that it is not seeking relief against "downstream products," but rather that it is not seeking relief against "downstream rubber products including, but not limited to, tires, belts, inner tubes and hoses." A chemical product such as 6PPD is not covered by this stipulation should the Commission find it a "downstream product" from 4-ADPA, a finding not necessarily mutually exclusive of the position taken by Flexsys here.

[18] In this respect, the ALJ's finding of a violation with respect to Sovereign is revealing. After finding that Sinorgchem's process for making 4-ADPA and 6PPD "literally infringes the asserted claims in issue," the ALJ found that Sovereign's importation into, and sale within the United States after importation of 6PPD purchased from Sinorgchem was "a violation of Section 337 since it involves infringement of ***at least*** method claim 61 of the '063 patent and method claim 11 of the '111 patent." ID at 102 (emphasis added). The ALJ apparently recognized the fact that Sovereign's importation and sale also could be seen as involving infringement of method claim 30 of the '063 patent and method claim 7 of the '111 patent. That he ultimately chose not to make this determination on the record because such additional finding was not needed to confirm a violation by Sovereign does not negate the fact that he apparently understood that infringement of these claims could be involved as well in the importation of the 6PPD.

made by means of the process covered by claim 30 of the '063 patent and claim 7 of the '111 patent – the process by which Sinorgchem produced the 4-ADPA that KKPC purchased, modified slightly, and sold for importation into the United States. ID at 104; *see also* 35-36.[19]

A similar question was presented to the Federal Circuit in a case involving 35 U.S.C. §271(g). *Eli Lilly*, 82 F.3d 1568. In that case, the patent covered a method for making "compound 6," from which the drug cefaclor could be produced by four additional process steps. *Id.* at 1570. The issue was whether the importation of cefaclor made from compound 6, which in turn was made by a process covered by the patent violated 35 U.S.C. §271(g). *Id.* at 1571. The Court denied Lilly's motion for a preliminary injunction, finding that Lilly could not prevail on whether compound 6 was "materially changed" by the subsequent process steps. *Id.* at 1573. Significantly, however, for the Court to have reached the material changed issue, it first had to find that cefaclor was made by the process that produced compound 6. In fact, the District Court in this case specifically found that: "there is little dispute among the parties that the first two prongs of section 271(g) are satisfied." *Eli Lilly & Co. v. American Cyanamid Co.*, 896 F. Supp. 851, 856 (S. D. Ind. 1995). Those first two prongs are parallel to Section 1337(a)(1)(B)(ii). Thus, had Lilly brought the action under Section 1337(a)(1)(B)(ii), it

[19] In this regard, given the express language of Section 1337(a)(1)(B)(ii), it is simply irrelevant that there was an intervening sale of the 4-ADPA from Sinorgchem to KKPC prior to the sale of the 6PPD into the United States by KKPC. The only relevant requirement in the statute is that there be a "sale for importation" into the United States "by the owner" (KKPC) "of articles that ... are made ... by means of a process covered by the claims of a valid and enforceable United States patent." 19 U.S.C. § 1337(a)(1)(B)(ii).

would have prevailed because the "materially changed" defense is not available. *Kinik,* 362 F.3d at 1361-64.

In *Bio-Technology*, 80 F.3d 1553, the Federal Circuit decided another case under Section 271(g) that is instructive on this issue. The question arose as to whether the imported product at issue in that case, human growth hormone ("hGH"), was "a product which is made by a process patented in the United States," even though the claim of the patent at issue was "directed to a method for producing a replicable cloning vehicle (*e.g.*, a plasmid), not hGH." *Bio-Technology*, 80 F.3d at 1560-1561. After noting that the statute did not specify what products will be considered to have been "made by" the patented process, the Federal Circuit affirmed the district court's conclusion that hGH was a product that was "made by" the '832 patented process under Section 271(g). *Id.* at 1561. The Federal Circuit agreed with the district court's reliance on certain legislative history to the Process Patents Amendment Act that indicated Congress intended to include this specific situation in the scope of Section 271(g). *Id.*

More significant, however, is the reasoning of the Federal Circuit as to how the legislative history was consistent with the statutory language. *Id.* The Federal Circuit expressly recognized that "[t]here is little doubt that the plasmid product of the claimed process and hGH are entirely different materials, one being more than materially changed in relation to the other. hGH is not a mere modification of the plasmid." *Id.* Nevertheless, the Federal Circuit reasoned that it was reasonable to interpret the scope of the statute to embrace a situation where the claimed process produced a product that in turn was further manufactured into a different product that then was imported, especially

where the patent at issue fully described how that process could be utilized to make the imported product:

> Moreover, the '832 patent itself explicitly contemplates that the patented process will be used as part of an overall process for producing hGH; indeed, the patent discloses in detail how to make hGH by carrying out the claimed process and other necessary steps. Thus, it cannot be said as a matter of law that the production of hGH is too remote from the claimed process of making a replication cloning vehicle. We therefore find no error in the court's conclusion that hGH is a product that is "made by" the '832 patented process.

Id.

Flexsys acknowledges that the decisions in E*li Lilly* and *Bio-Technology* are not controlling precedent here. But the language of Section 1337(a)(1)(B)(ii) excluding from importation products made by processes covered by United States patents is the same in effect as the language of Section 271(g). *See Amgen,* 902 F.2d at 1540, n.13 (comparing the two sections). A major difference between the two statutes is that the "materially changed" defense of Section 271(g) is not available under Section 1337(a)(1)(B)(ii). *Kinik,* 362 F.3d at 1361-64. Nothing in the plain language of Section 1337(a)(1)(B)(ii) makes an exception for imported "articles" that have been subjected to additional process steps, especially where, as here, the patent claims use the word "comprising" and cover processes in which additional steps may be used.

In the Initial Determination in this case, the ALJ found that Sinorgchem's process for making 4-ADPA was covered by claim 30 of the '063 patent and claim 7 of the '111 patent. KKPC's additional process step to convert Sinorgchem's 4-ADPA into 6PPD is irrelevant on the issue of whether its importation of such 6PPD constitutes importation of an article made by a process covered by claim 30 of the '063 patent or claim 7 of the '111 patent. Both the '063 patent and the '111 patent disclose in detail how to make 6PPD by

carrying out the claimed process and other necessary steps. Thus, the Commission should follow the same reasoning here as the Federal Circuit did in *Bio-Technology* and conclude that it cannot be said as a matter of law that the production of KKPC's 6PPD is too remote from the claimed process of making 4-ADPA for it not to be considered an article "made . . . by means of . . . a process covered by the claims of a valid and enforceable United States patent" within the plain meaning of Section 1337(a)(1)(B)(ii). Based on this reasoning and conclusion, the Commission should reverse the decision of the ALJ and find that KKPC violated the Tariff Act by its sale of this 6PPD for importation into the United States.

IV. CONCLUSION

For the reasons set forth above, the Commission should hold that Section 1337(a)(1)(B)(ii) requires only that the article imported or sold for importation into the United States be made by a process covered by the claims of a valid and enforceable United States patent, regardless of how many entities practice the various steps set forth in the claims of the patent. Based on this holding, the Commission should find that KKPC has violated Section 1337(a)(1)(B)(ii) by selling for importation into the United States a product – 6PPD – that is made by a process covered by claims 30 and 61 of the '063 patent and by claims 7 and 11 of the '111 patent.

In addition, the Commission should find that KKPC's importation of 6PPD is a violation because it constitutes the importation of an article made by a process covered by claim 30 of the '063 patent and claim 7 of the '111 patent.

Judge Luckern's ID should be affirmed in all other respects.

Dated: March 13, 2006

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the attached was served as indicated on the parties listed below this 13th day of March 2006:

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